UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

THE UNITED STATES OF AMERICA, *ex rel.* HILLARY ESTRIGHT, Plaintiff and Relator, v. CVS PHARMACY, INC., *et al.*, Defendants.	Civil Action No. 22-CV-222-WES-PAS

UNITED STATES'S OPPOSITION TO CVS'S MOTION TO DISMISS

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I. OVERVIEW OF ARGUMENT

For decades, the Controlled Substances Act ("CSA") has imposed a framework of legal obligations to prevent the diversion and abuse of highly dangerous, addictive drugs, like opioids. Those obligations apply to manufacturers, distributors, prescribers, and pharmacies and pharmacists—each a key player in ensuring that controlled substances are used only for legitimate medical purposes. CVS Pharmacy, Inc. and the related CVS defendants ("CVS" or "Defendants") have long been aware of their obligations under the CSA: pharmacies may not knowingly fill invalid prescriptions, and pharmacists must adhere to their own professional obligations. As the Government's Complaint in Intervention ("Complaint" or "Compl.," ECF No. 52) details, Defendants violated the CSA chainwide, for years, by knowingly filling invalid prescriptions. CVS then violated federal law again each time it submitted invalid controlled substance prescriptions to Medicare, Medicaid, or TRICARE (collectively "Federal Healthcare Programs") for reimbursement in violation of the Federal False Claims Act ("FCA") and common law, knowing that the prescriptions were not valid, were not for a medically accepted indication, and/or were not medically necessary.

CVS now seeks to dismiss the Complaint in part. Significantly, CVS concedes that examples of CSA violations for claims in Attachment 1 that are based on the alleged knowledge of CVS's pharmacists, rather than the knowledge of CVS's corporate personnel, are adequately pled. CVS asks the court to dismiss all other alleged CSA violations, including all prescriptions set forth as examples in Attachment 2. With respect to the Government's FCA claims, CVS acknowledges that the Government has adequately pled FCA violations exemplified by the claims listed on Attachment 1 and for Patients #1 through #6, but seeks to dismiss all other alleged FCA

violations, including those tied to Patients #7 through #10 in Attachment 1 and all of those claims set forth as examples in Attachment 2.

CVS's Motion fails for a number of reasons, and the Complaint should be allowed to proceed in full.

First, CVS seeks to dismiss any alleged violations of the CSA for "red flag" prescriptions, arguing that these violations are insufficiently pled because red flag prescriptions are not *per se* invalid and because the Government did not provide sufficient details about the prescribers. But the Complaint alleges that the identified prescriptions bore unresolved red flags that were so egregious that any trained, professional pharmacist would recognize the prescriptions were invalid, and that CVS created an environment that put profits over safety and led its pharmacists to routinely, knowingly fill these red flag prescriptions in violation of the CSA.

Second, CVS argues that any alleged violations that rely on the knowledge of employees other than the dispensing pharmacist about seven "pill mill" practitioners' invalid prescribing practices must be dismissed because only the dispensing pharmacist's knowledge is relevant under the CSA. The plain language of the statute and regulations, as well as the case law, contradict CVS's argument. The Complaint is replete with details establishing that CVS's compliance and other corporate personnel knew about pill mill prescribers and either refused to share that information with pharmacists or instructed pharmacists to continue filling the pill mill prescriptions.

Third, the Government alleges that CVS improperly refilled certain controlled substances contrary to regulatory requirements. CVS seeks to dismiss those claims, asserting that the Complaint contains "no facts" to support the allegations. Taken as a whole, however, the Complaint more than plausibly alleges that CVS violated the CSA's restrictions on refills.

Fourth, with respect to the FCA allegations, CVS's Motion incorrectly treats the Government's FCA claims as "derivative of [] its theory under the CSA" and argues that the Government has not pled falsity with adequate specificity because the Government has not alleged that all prescribers who wrote the prescriptions did so unlawfully. ECF No. 65-1 at 25. This argument mischaracterizes the Complaint and seeks to impose a non-existent and irrelevant pleading requirement: the FCA claim is separate from the CSA claim. Even though certain elements of both claims may rely on similar factual proof at trial, the CSA and the FCA are two separate statutes, and a finding that CVS violated the CSA is not a prerequisite for an FCA violation. In particular, if CVS "knowingly," as that term is more broadly defined in the FCA, fills a prescription that is not reimbursable by Federal Healthcare Programs, then the submission of a claim to the Government for that prescription violates the FCA, even if, for some reason, the filling of the prescription did not violate the CSA. Thus, because the Government is alleging FCA violations against ***CVS*** and not individual prescribers, the focus must be on the actions and knowledge of ***CVS personnel only***; facts regarding the individual prescribers are not necessary to plead or prove violations against CVS.

Fifth, the Government has plausibly alleged that the fact that controlled substance prescriptions were invalid, lacked a medically accepted indication, and/or were not medically necessary was material to the Federal Healthcare Programs' decisions to pay for such claims. CVS's assertion that the Government has not adequately alleged materiality because the Federal Healthcare Programs had certain data for the prescriptions at issue is incorrect. As alleged in the Complaint, CVS had information that the Federal Healthcare Programs did not possess. Moreover, the analysis of materiality is "holistic" and requires a review of the totality of the circumstances. *See United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 109-11 (1st Cir. 2016)

(reviewing a variety of factors and finding that "awareness of allegations" that the defendant violated regulations was not actual "knowledge").

Last, CVS's argument seeking dismissal of the Government's common law claims fails because the Government may plead claims for fraud, payment by mistake, and unjust enrichment in the alternative to its FCA claims. For these reasons and those set forth below, the Complaint plausibly alleges that CVS violated the CSA, FCA, and common law. CVS's arguments to the contrary lack merit, and its Motion should be denied in full.

II. STATUTORY AND REGULATORY BACKGROUND

A. The Controlled Substances Act

The CSA and accompanying regulations establish a comprehensive regime for combatting drug abuse. *See* Compl. ¶ 34; 21 U.S.C. § 801 *et seq.*; *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). The CSA makes it unlawful for any registrant to "dispense a controlled substance in violation of [21 U.S.C. §] 829. . . ."[1] 21 U.S.C. § 842(a)(1). In turn, 21 U.S.C. § 829 and the implementing regulations set forth the rules regarding the dispensing of prescription drugs. Most controlled substances may be dispensed only pursuant to prescriptions that are "effective," meaning valid. Compl. ¶ 39; 21 C.F.R. § 1306.04(a); 21 U.S.C. §§ 829(a)-(b).[2] To be effective, controlled substance prescriptions must be issued by an individual

[1] Employees of a Drug Enforcement Administration ("DEA") registered dispenser, such as a pharmacy, may dispense controlled substances under the dispenser's registration. 21 U.S.C. § 822(c)(1).

[2] While prescriptions are generally required to dispense prescription drugs, *see, e.g.*, 21 U.S.C. § 353(b), the CSA itself does not require prescriptions for Schedule V controlled substances. *See* 21 U.S.C. § 829(c). Nonetheless, dispensing such drugs "other than for a medical purpose" violates § 829. *Id.* Dispensing a Schedule V drug when the pharmacist knows the drug is not for

practitioner "for a legitimate medical purpose" and in the "usual course" of the practitioner's "professional practice." 21 C.F.R. § 1306.04(a). While "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," a "corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* "[T]he person knowingly filling" an invalid prescription is subject to penalties. *Id.*

B. The False Claims Act

The FCA, 31 U.S.C. § 3729 *et seq.*, is the United States's primary tool to redress fraud on the Government, including fraud involving Federal Healthcare Programs. The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. §§ 3729(a)(1)(A)-(B); Compl. ¶ 55. The touchstone for FCA liability is whether the defendant knowingly caused the Government to pay money it should not have. "Knowingly" is defined to include not only actual knowledge, but also "reckless disregard" and "deliberate ignorance." 31 U.S.C. § 3729(b)(1); Compl. ¶ 56. The Supreme Court has said that "Congress wrote [the FCA] expansively," with the intent "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

C. Federal Healthcare Programs

The Federal Healthcare Programs at issue in this case are Medicare, Medicaid, and TRICARE. Medicare is a federally funded health insurance program for the elderly and disabled

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legitimate medical purpose thus violates 21 U.S.C. §§ 842(a)(1) & 842(c)(1)(A), just as when the pharmacist does the same for a controlled substance in Schedules II through IV pursuant to an invalid prescription under 21 C.F.R. § 1306.04(a).

administered by the Department of Health and Human Services ("HHS") through the Centers for Medicare & Medicaid Services ("CMS"). Medicare Part D is a voluntary prescription drug benefits program for Medicare enrollees. Compl. ¶ 59. CMS contracts with private entities known as Part D Plan "Sponsors" to administer Part D plans. *Id.* ¶ 60. Plan Sponsors, in turn, enter into subcontracts with pharmacies or other downstream entities, including Pharmacy Benefit Managers ("PBMs"), to provide prescription drugs to the Part D beneficiaries in their plans. *Id.* ¶ 61.

After a pharmacy requests payment, a Plan Sponsor creates a Prescription Drug Event ("PDE") record and submits it to CMS for every prescription filled. *Id.* ¶¶ 62-64. A Plan Sponsor must expressly certify the accuracy, completeness, and truthfulness of all data related to the payment and also agrees to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. §§ 423.505(h)(1), (k)(1), (k)(3); Compl. ¶¶ 74-76. All subcontracts between Plan Sponsors and downstream entities (including pharmacies like CVS) must contain language obligating those entities to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv); Compl. ¶ 75. Compliance with the requirement that PDE data submitted is "accurate, complete, and truthful" is a condition of payment under Medicare and material to the Government's payment decision. 42 C.F.R. § 423.505(k)(2); Compl. ¶ 79.

Medicaid is a jointly funded, state-administered program that provides health care benefits primarily for low-income and disabled patients. Compl. ¶ 85. Providers who participate in the Medicaid program, like CVS, must sign enrollment agreements in which they certify compliance with state and federal Medicaid requirements. *Id.* ¶ 89. These agreements typically require compliance with all state and federal laws and Medicaid regulations in billing for services or supplies and, in many states, also require an affirmative certification of such compliance as a condition of payment of the claims submitted for reimbursement by Medicaid. *Id.* ¶ 90.

TRICARE is part of the United States military's healthcare system. *Id.* ¶ 91. TRICARE contracts with PBMs to administer its pharmacy programs. *Id.* After receiving a claim for a prescription event, the PBM sends TRICARE an electronic record, TRICARE Encounter Data ("TED"), with information regarding the prescription. *Id.* ¶ 94. TRICARE authorizes payment based on the TED. *Id.* ¶ 95. Pharmacies that provide services to TRICARE beneficiaries must comply with the program's requirements, including its anti-abuse provisions. *Id.* ¶ 96; 32 C.F.R. §§ 199.9(a)(4), (b), (c)(2).

III. FACTUAL BACKGROUND

CVS is the largest pharmacy chain in the United States, operating more than 9,000 pharmacies, and is among the top dispensers of opioids in the country. Compl. ¶¶ 2, 21-23. CVS and its pharmacists serve as critical gatekeepers against the unlawful dispensing of opioids and other controlled substances. *Id.* ¶¶ 6-7. CVS knew the law required it to prevent the diversion of controlled substances and to refrain from filling invalid prescriptions, and CVS implemented policies and training outlining these legal obligations. *Id.* ¶¶ 34-54. As alleged throughout the Complaint, however, CVS violated those obligations by filling prescriptions for opioids, and other highly diverted controlled substances, without resolving red flags that indicated the prescriptions were not valid, lacked a medically accepted indication, and/or were not issued for a legitimate medical purpose. *Id.* ¶¶ 8-9, 13-14, 105-06, 110-16. For the prescriptions that CVS subsequently submitted to Federal Healthcare Programs for payment, CVS's compliance with federal and state requirements relating to pharmacies' dispensing of controlled substances was material to the Government's reimbursement decision. *Id.* ¶¶ 97-104, 117.

CVS pharmacists knowingly filled prescriptions for controlled substances that had clear unresolved red flags that were highly indicative of unlawfulness. These red flags included: (1)

prescriptions for the "trinity," a widely known and dangerous combination of an opioid, benzodiazepine, and muscle relaxant that creates a very high risk of abuse and overdose; (2) early fills of opioid prescriptions before a prior prescription for the same drug had run out, which is a clear sign of overutilization; (3) prescriptions for extremely high doses and excessive quantities of opioids that fed opioid dependence and addiction; and (4) prescriptions written by pill mill prescribers whom CVS's own pharmacists had repeatedly identified as writing illegitimate prescriptions with no medically valid purpose. *Id.* ¶¶ 105-17. In addition, CVS pharmacists filled or refilled Schedule III and IV drug prescriptions more than six months after the prescription date or refilled such controlled substances more than five times after the prescription date without the prescriber renewing the prescription. *Id.* ¶¶ 53-54, 115, 219, 372.

CVS pharmacists knowingly filled these invalid prescriptions, despite their training and experience, because CVS had implemented performance metrics and incentive compensation policies that pressured and incentivized pharmacists to fill prescriptions as quickly as possible, without properly assessing the prescriptions' legitimacy. *Id.* ¶¶ 118-50. CVS's corporate personnel knew that pharmacists were filling prescriptions bearing one or more unresolved red flags without adequate time to assess the validity of the prescriptions; pharmacy employees reported that severe understaffing led to a "major public safety risk," *id.* ¶ 169, and "an increased risk for medication errors" and errors so severe that they could be "harmful or event fatal to . . . patients." *Id.* ¶¶ 171-173; *see also id.* ¶¶ 151-205. Taken together, and as true, these allegations demonstrate that CVS knew its pharmacists filled thousands of invalid prescriptions for controlled substances, many of which were submitted for payment to Federal Healthcare Programs. *Id.* ¶¶ 211-16. As plausibly pled in the Complaint, Defendants violated the CSA, FCA, and common law.

IV. STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure ("Rule") 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This "does not impose a probability requirement at the pleading stage; it simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of illegal" conduct. *Twombly*, 550 U.S. at 556. In evaluating a complaint under Rule 12(b)(6), a court must accept the truth of the allegations and construe them in the plaintiff's favor. *Gargano v. Liberty Int'l Underwriters*, 572 F.3d 45, 48 (1st Cir. 2009).

The Government must plead FCA claims with particularity under Rule 9(b). Under Rule 9(b), the Government is only required to allege with particularity those facts that constitute a defendant's "fraud or mistake," but *not* the defendant's knowledge. *See*, *e.g.*, *United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 731 (1st Cir. 2007). "[T]he specificity requirement extends only to the particulars of the allegedly misleading statement itself. The other elements of fraud, such as intent and knowledge, may be averred in general terms." *Rodi v. S. New Eng. Sch. of L.*, 389 F.3d 5, 15 (1st Cir. 2004) (citations omitted).

While a party must specifically identify the "who, what, when, where, and how" of the alleged fraud, Rule 9(b) does not call for a "checklist of mandatory requirements." *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016). Instead, a court must "[v]iew[ ] the complaint holistically" to determine whether it has pled "sufficient facts to provide fair notice to the defendant[ ] and state a facially plausible legal claim." *Garcia-Catalan v. United States*, 734 F.3d 100, 103 (1st Cir. 2013) (alteration in original, internal quotation and citation omitted).

Significantly, the Government need not "establish" anything at the pleading stage. *See Iqbal*, 556 U.S. at 678-79; *Rodriguez-Reyes v. Molina-Rodriguez*, 711 F.3d 49, 54 (1st Cir. 2013). That is reserved for trial. At the pleading stage, the allegations need not establish that the prescriptions were invalid, but only plausibly allege so. *See Sepulveda-Villarini v. Dep't of Educ. of Puerto Rico*, 628 F.3d 25, 30 (1st Cir. 2010) ("A plausible but inconclusive inference from pleaded facts will survive a motion to dismiss."). The plausibility standard has been satisfied so long as the Complaint alleges facts that, "taken in their entirety," are sufficient to support the necessary inferences. *See Rodriguez-Reyes*, 711 F.3d at 54-57. To hold otherwise, as CVS asks this Court to do, would "test[] the complaint in a crucible hotter than the plausibility standard demands." *Id.* at 53.

V. ARGUMENT

A. Defendants Attempt To Improperly Restrict the Government's Case to the Alleged Examples of CVS's Widespread Violations.

Importantly, CVS acknowledges that, for both the CSA and FCA, the Government has met its pleading burden with respect to the example prescriptions in Attachment 1 that are based on individual pharmacists' scienter and for Patients #1 through #6. ECF No. 65-1 at 3-5. By asking the Court to dismiss "[a]ll CSA and FCA claims based on the prescriptions listed in Attachment 2" and "all CSA claims based on the prescriptions listed in Attachment 1 . . . to the extent they are based on the alleged scienter of CVS personnel at corporate headquarters," *id.* at 9, CVS implies that these attachments comprise *all* the alleged violations pled by the Government. This contention mischaracterizes the Complaint, which identifies Attachments 1 and 2 as providing examples of CVS's alleged, widespread violations. It also ignores civil pleading standards.

CVS apparently seeks a ruling on its Motion that would require the Government to plead every invalid prescription that CVS dispensed in violation of the CSA or FCA. But this Court and

others have repeatedly upheld broad complaints under Rule 12(b)(6), and the more exacting Rule 9(b) standard applicable to the FCA, where only a few specific claims were identified. *See, e.g. United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 37-41 (1st Cir. 2017) (FCA complaint alleging fraudulent scheme to sell defective medical devices met Rule 9(b) with only one identified claim for government reimbursement); *United States v. Journey to Hope, Health & Healing*, 728. F. Supp. 3d 251, 262-63 (D.R.I. 2024) (FCA complaint alleging a six-year fraud scheme that identified only three patients for whom claims were submitted without proper treatment plans sufficient under Rule 9(b)); *United States ex rel. Souza v. Embrace Home Loans*, No. 22-cv-00453, 2023 WL 4234967, at *2-3 (D.R.I. June 28, 2023) (complaint alleging a pattern of issuing loans ineligible for government insurance across 54 branches around the country with a sample of 40 allegedly ineligible loans sufficient under Rule 9(b)); *United States ex rel. Carbon v. Care New England Health Sys.*, 567 F. Supp. 3d 355, 360-62 (D.R.I. 2021) (identifying three patients subject to the fraud scheme and only one insured by Medicare sufficient under Rules 12(b)(6) and 9(b)); *United States v. Howen*, No. 21-cv-00106, 2022 WL 18420744, at *6-7 (E.D. Cal. Aug. 9, 2022) (rejecting defendant's proposed CSA pleading standard requiring detailed factual allegations "as to each allegedly invalid prescription dispense[d]" and permitting alleged violations to be combined into a single count); *United States v. Ridley's Family Mkts., Inc.*, No. 20-cv-173-TS-JCB, 2021 WL 2322478, at *3 (D. Utah June 7, 2021) ("pleading standards do not *require* the United States to identify specific pharmacists or specific prescriptions to state a plausible claim") (emphasis in original); *In re Nat'l Prescription Opiate Litig*. ("*Opiate I*"), 477 F. Supp. 3d 613, 629 n.25 (N.D. Ohio 2020) (failure to identify any specific prescription did not support dismissal at the motion to dismiss stage).

Moreover, CVS's claim in a footnote—that the Complaint must plead each invalid prescription that is an alleged violation of the CSA, FCA, or common law as a separate count pursuant to Rule 10(b) (ECF No. 65-1 at 8 n.4)—is contrary to the language of Rule 10(b) and the weight of the above case law. Rule 10(b) provides that a "party must state its claims or defenses in numbered paragraphs, each limited as far as practicable to a single set of circumstances." Fed. R. Civ. P. 10(b). The rule then states that "each claim founded on a separate transaction or occurrence . . . must be stated in a separate count or defense" only when doing so "would promote clarity." *Id.* Here, separating the many claims alleged to have resulted from CVS's overarching violative course of conduct into separate counts, far from providing greater clarity, would result in hundreds of thousands of counts—resulting in more bulk and complexity with less specificity and clarity. Moreover, as noted above, courts have repeatedly rejected this unwieldy view of pleading.

Because the Complaint's allegations satisfy Rule 9(b)'s heightened pleading standard for the FCA claims, they also satisfy Rule 8's lesser requirement of providing fair notice as to the CSA claims. Neither requires the Government to allege every violation that CVS committed over a decade. The Complaint's allegations "raise a reasonable expectation that discovery will reveal evidence of illegal" conduct. *Twombly*, 550 U.S. at 556. Nothing more is required.

B. <u>The Complaint Plausibly Alleges That CVS Violated the CSA.</u>

The Complaint alleges that CVS filled thousands of prescriptions that its employees knew were invalid either because the prescriptions bore such blatant "red flags" on their face—dangerous drug combinations, extremely high doses and quantities, repeated early fills, or non-compliance with CSA refill requirements—or because they were written by practitioners known to be pill mill prescribers, or both. Compl. ¶¶ 217-369. CVS now attempts to distract from more than a decade of its failures by arguing that the Complaint does not include sufficient facts about the prescribers who wrote the blatant "red flag" prescriptions and that CVS's corporate personnel's

knowledge of pill mill prescribers' practices somehow does not qualify as knowledge under the CSA. CVS is wrong on both fronts.

1. The Complaint Adequately Alleges CVS Knowingly Filled Red Flag Prescriptions.

First, CVS asserts that red flag prescriptions are not sufficiently pled because the Government did not allege "a single fact about the doctors" writing the prescriptions. ECF No. 65-1 at 13. Next, CVS argues that because red flag prescriptions are not *per se* illegal, this alone "mandates dismissal" of the Government's allegations. *Id.* at 16. But this case is not about practitioners' conduct, and it is not about "per se" illegal red flag prescriptions; neither is pled by the Government because neither is the basis of CVS's liability under the CSA.

a. The CSA Requires Pharmacies and Pharmacists to Resolve Red Flags.

Under the CSA, pharmacies and pharmacists may not fill controlled substance prescriptions they know are invalid, including prescriptions not issued for a legitimate medical purpose or in the usual course of a practitioner's professional practice. *See* 21 U.S.C. § 829; 21 C.F.R. § 1306.04(a). Part and parcel to this requirement, "[a] pharmacist or pharmacy may not dispense a prescription in the face of a red flag . . . unless [she or] he or it takes steps to resolve the red flag and ensure that the prescription is valid." *In re Holiday CVS, L.L.C.* ("*Holiday CVS*"), 77 Fed. Reg. 62316-01, 62341 (Drug Enf't Admin. Oct. 12, 2012) (Decision and Order). The same is true of pharmacies. *See The Cherokee Nation v. CVS Pharm., Inc.*, No. 18-cv-00056-RAW, 2021 WL 1200093, at *6 (E.D. Okla. Mar. 29, 2021) ("[T]he court concludes that *pharmacies*, not merely pharmacists, have obligations to 'resolve red flags' before dispensing controlled substances concerning suspicious prescriptions.") (emphasis in original) (quoting *Holiday CVS*, 77 Fed. Reg. at 62317-23). This obligation not only requires pharmacists and pharmacies to resolve known red flags, but also prohibits them from ignoring red flags and turning a blind eye to whether a

prescription is invalid. *See Ridley's Family Mkts., Inc.*, 2021 WL 2322478, at *2 n.15 (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011)); *see also Suntree Pharm. & Suntree Med. Equip., LLC*, 85 Fed. Reg. 73753-01, 73769 (Drug Enf't Admin. Nov. 19, 2020) (Decision and Order) ("DEA has also consistently interpreted the corresponding responsibility regulation such that '[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescription.'") (citation omitted).

The Complaint alleges in extensive detail that CVS and its pharmacists knowingly and routinely filled prescriptions that a reasonable pharmacist would recognize as invalid given the presence of egregious red flags of diversion or abuse. Compl. ¶¶ 105-17, 318-68. These red flags include trinities, early fills of opioids, extremely high doses and excessive quantities of opioids, and prescriptions written by pill mill prescribers, among others. *Id.* ¶¶ 105-17. The unambiguous and serious nature of the alleged red flags, including but not limited to those underlying the prescription examples in Attachment 2, informed the dispensing pharmacist and pharmacy that it was not only plausible, but also highly likely that these prescriptions were invalid. *See, e.g., id.* ¶¶ 238, 293, 298, 322, 327, 328. For example, Attachment 2 identifies at least 65 red flag prescriptions filled by CVS for Patient #7 and further shows that, between October 2020 and June 2022, CVS filled at least 14 same-day trinity prescriptions for Patient #7. *Id.* ¶¶ 357-59.

Further, as alleged, CVS pharmacists failed to resolve red flags and filled the invalid prescriptions contrary to the CSA and their professional obligations because CVS created a work environment plagued with chronic understaffing and performance metrics focused on speed rather than safety. *Id.* ¶¶ 115-50. "CVS knew that its pharmacists were filling prescriptions at unsafe speeds at the expense of public health and legal compliance but continued to enforce the staffing

levels and employment policies that drove improper dispensing." *Id.* ¶ 151. These facts are more than sufficient to meet the CSA pleading standards. *See*, *e.g.*, *Ridley's Family Mkts., Inc.*, 2021 WL 2322478, at *2 & n.18 (citing cases); *Opiate I*, 477 F. Supp. 3d at 629 n.25, 630; *Howen*, 2022 WL 18420744, at *6-7.

b. CVS Improperly Focuses on Practitioners' Conduct Rather Than Its Own.

CVS ignores the evidence of red flag prescriptions' invalidity and CVS's and its pharmacists' knowledge of that invalidity pled throughout the Complaint. Instead, CVS argues that the allegations are deficient because the Government "must allege facts showing that the prescribing doctors wrote the prescriptions unlawfully" as a "prerequisite" for CSA claims. ECF No. 65-1 at 1. This simply is not correct.

Courts have found that pharmacies and pharmacists violated § 1306.04(a) by failing to resolve red flags and dispensing invalid prescriptions independent of the underlying practitioner's conduct. In 2008, for example, the Sixth Circuit upheld a decision that Medicine Shoppe, a pharmacy in Tennessee, "fell asleep at the wheel by honoring prescriptions no reasonable pharmacist would fill without further inquiry," including prescriptions for "a dozen patients to whom Medicine Shoppe dispensed drugs despite obvious warning signs of 'doctor shopping.'" *Med. Shoppe-Jonesborough v. Drug Enf't Admin.*, 300 F. App'x 409, 413 (6th Cir. 2008). For instance, the pharmacy filled prescriptions for one patient issued by "21 different prescribers for an array of identical, overlapping or incompatible drugs, resulting in quantities and combinations that the government's experts concluded would be toxic and potentially devastating for the patient." *Id.* (internal quotations omitted). The identities of the 21 prescribers and whether they each knew of the patient's doctor-shopping was not at issue, and the court affirmed DEA's finding that Medicine Shoppe was liable for filling the invalid prescriptions. *Id.*

Similarly, in *Jones Total Health Care Pharm., LLC v. Drug Enf't Admin.*, the Eleventh Circuit upheld the DEA's decision to suspend a pharmacy's registration based, in part, on the owner-pharmacist's own statement that she "continued to struggle with the idea that pharmacists have an independent duty, apart from the prescribing physician, to ensure that prescriptions are issued for medically legitimate purposes before filling them." 881 F.3d 823, 832 (11th Cir. 2018). The pharmacy was held liable for filling prescriptions with "obvious and unresolvable" red flags, such as prescriptions for immediate release "cocktail" pain medications, such as oxycodone and Xanax, known for their abuse potential. *Id.* at 827-28. Again, the prescribers' identities, as well as other facts about the prescribers' practices or "bases for their prescribing decisions," ECF No. 65-1 at 10, were irrelevant. The Eleventh Circuit reasoned, "pharmacists do not need to practice medicine or independently examine a patient in order to determine in certain cases that a prescription was not issued for a legitimate medical purpose." *Jones*, 881 F.3d at 832.[3]

Ignoring these civil cases, CVS relies on criminal cases against individual providers to suggest that the CSA requires the Government to plead the identities and activities of each prescriber. *See* ECF No. 65-1 at 11-12 (citing *United States v. Moore*, 423 U.S. 122, 138 (1975); *Ruan v. United States*, 597 U.S. 450, 454 (2022); *United States v. Okafor*, No. 23-cr-116-JDB, 2025 WL 385782, at *1 (D.D.C. Feb. 4, 2025)). But the cases CVS cites address the criminal standard of proof under 21 U.S.C. § 841 against physicians for improper prescribing, ECF No. 65-1 at 18-19, not the civil pleading standard against pharmacies for dispensing controlled substances in violation of 21 U.S.C. § 829. CVS's argument that the Government is required to plead specific

[3] Moreover, in *Ridley's Family Mkts., Inc.*, the court held that the Government sufficiently pled that the pharmacy was potentially liable for filling forged prescriptions, as well as prescriptions with various other red flags. 2021 WL 2322478, at *3. Those forged prescriptions were invalid without any involvement of a prescriber.

unlawful conduct by doctors in this context is therefore incorrect.

c. Prescriptions with Egregious Red Flags are Sufficient to Plausibly Allege Invalidity.

CVS further asserts that the Complaint is deficient because red flags are not "dispositive of illegitimacy." ECF No. 65-1 at 18. CVS argues that prescriptions for things such as "excessive quantities of opioids" *could* be valid and that DEA has acknowledged that red flags alone are not conclusive of invalidity. *Id.* at 16-17. But the Government is not alleging "per se" illegality for all prescriptions with any red flag. The Complaint alleges that, in fact, CVS did not resolve the pled red flags and that the prescriptions were invalid. Compl. ¶¶ 7, 13, 47, 109, 211, 325.

Moreover, CVS's suggestion that the prescriptions in Attachment 2 could be valid, ECF No. 65-1 at 17, is an assertion of fact contrary to the Complaint's allegations. Suggestions of hypothetical factual scenarios, especially those contrary to the facts alleged, cannot carry the day for CVS. *See Sepulveda-Villarini*, 628 F.3d at 30 ("[a] plausible but inconclusive inference from pleaded facts will survive a motion to dismiss.").

Further undercutting CVS's position, numerous courts have recognized red flags to be highly indicative of invalid prescribing and therefore sufficient to plausibly allege a prescription's invalidity. In *Howen*, for instance, the court concluded that the Government plausibly stated a claim with allegations that the "presence of red flags" show "that that defendants had the requisite knowledge that they were dispensing controlled substances pursuant to illegitimate prescriptions in violation of § 1306.04(a)." 2022 WL 18420744, at *8; *see also United States v. City Pharm.*, No. 16-cv-24, 2017 WL 1405164, at *4 (N.D.W. Va. Apr. 19, 2017) (granting summary judgment against a pharmacist for violating 21 U.S.C. § 842(a)(1), concluding that the "red flags [were] so obvious that only those who [were] deliberately ignorant would fill the prescription") (citation omitted), *aff'd sub nom. United States v. Wasanyi*, 801 F. App'x 904 (4th Cir. 2020); *see also*

Suntree Pharm., 85 Fed. Reg. at 73769-70, 73764-65 (finding blatant red flags, including excessive doses, early fills, and highly abused drug combinations, to be substantial circumstantial evidence of the prescriptions' invalidity). Likewise, in *Ridley's Family Mkts., Inc.*, the court denied the defendant pharmacy's motion to dismiss, holding that the Government plausibly stated a CSA claim by "describ[ing] numerous red flags" that Ridley's pharmacists encountered and "failed to investigate . . . before filling the related prescriptions." 2021 WL 2322478, at *2.

In fact, pharmacists and pharmacies have been convicted criminally for knowingly filling invalid prescriptions based on the presence of unresolved red flags that evidenced the prescriptions' illegitimacy. *See United States v. Otuonye*, 995 F.3d 1191, 1200-01, 1211 (10th Cir. 2021) (affirming conviction of pharmacist who filled prescriptions in the face of red flags, including high doses and dangerous drug combinations "that should have alerted" the pharmacist they were issued "outside the usual course of professional medical practice and without a legitimate medical purpose"); *United States v. Jones*, 825 F. App'x 335, 338-39 (6th Cir. 2020) (affirming pharmacist's conviction for dispensing controlled substances despite red flags, including for long-term, dangerous combinations, which indicated no legitimate medical purpose); *United States v. Lawson*, 682 F.2d 480, 482-83 (4th Cir. 1982) (affirming pharmacist's conviction for dispensing controlled substances in excessive quantities that "belied any conclusion that the prescriptions . . . were ordered for individual patients"). Certainly, if red flags can be proof of invalidity beyond a reasonable doubt, they are sufficiently probative of invalidity to meet the civil pleading standard that controls here.

2. The Government Adequately Alleges CVS Knew Pill Mill Prescriber Prescriptions Were Invalid.

CVS next argues that it cannot face liability for prescriptions written by pill mill prescribers if the individual, dispensing pharmacist was unaware of a prescription's invalidity. ECF No. 65-1

at 19. CVS argues that, for such prescriptions, the knowledge of CVS's corporate personnel is not relevant to CSA liability. *Id.* at 22. CVS concedes that the Government has adequately alleged violations if the dispensing pharmacist knew the prescriber was a pill mill. *See id.* at 4.

As a threshold matter, "Rule 12(b)(6) doesn't permit piecemeal dismissals of *parts* of claims." *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015) (emphasis in original); *Fujifilm N. Am. Corp. v. M&R Printing Equip., Inc.*, 565 F. Supp. 3d 222, 231 (D.N.H. 2021) ("At this early stage, [plaintiff] need only allege a set of facts showing … that *a* theory exists upon which [plaintiff] may be able to hold defendants liable.") (internal quotation and citation omitted); *cf.* Fed. R. Civ. P. 56(a). CVS's Motion, however, seeks to do just that by arguing that certain pill mill prescriber CSA violations are adequately pled but others are not.

Setting this aside, CVS is simply wrong on the law. First, the CSA's corresponding responsibility obligation applies to both pharmacists and pharmacies. Second, CVS is incorrect that liability can only attach where knowledge of invalidity lies with the dispensing pharmacist.

a. CVS is a "Person" Under § 1306.04.

The Complaint alleges that CVS's DEA-registered pharmacies "continued to fill prescriptions that were not valid, not for a medically accepted indication, were not medically necessary, and/or were written outside the ordinary course of medicine" by "prescribers that CVS knew to be engaged in pill mill practices." Compl. ¶ 217.

CVS, as an operator of DEA-registered pharmacies, has a corresponding responsibility in dispensing controlled substances. The plain language of the CSA makes this clear: 21 U.S.C. § 842(a)(1) makes it unlawful for any "person" to knowingly "distribute or dispense a controlled substance in violation of [21 U.S.C. §] 829." *See also* 21 C.F.R. § 1306.04(a) ("*[T]he person* knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of provisions of law relating to controlled substances.") (emphasis added). Indeed, CVS

itself has previously, expressly acknowledged that the company itself—not just its pharmacists—has this corresponding responsibility. *See* Compl. ¶ 51.[4]

Courts that have considered the issue all agree: the pharmacy, in addition to the pharmacist, is subject to the requirements of § 1306.04(a). *See*, *e.g.*, *In re Nat'l Prescription Opiate Litig.* ("*Opiate III*"), 589 F. Supp. 3d 790, 817-18 (N.D. Ohio 2022) (rejecting idea that the CSA imposes corresponding responsibility only upon pharmacists but "no corporate-level responsibility upon a Pharmacy that may employ thousands of pharmacists across the country" as defying "logic and common sense."); *City & Cty. of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 670-71 (N.D. Cal. 2020) (rejecting claim that § 1306.04(a) does not impose "actionable duty on pharmacies, just pharmacists."); *Ridley's Family Mkts., Inc.*, 2021 WL 2322478, at *2-3 (same); *The Cherokee Nation*, 2021 WL 1200093, at *6.

DEA, the agency responsible for enforcing the CSA, agrees that § 1306.04 applies equally to pharmacists and pharmacies. "DEA has expressly and consistently ruled that '[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'" *Opiate III*, 589 F. Supp. 3d at 818 (citation omitted). In *Holiday CVS*, the Administrative Law Judge identified DEA's "Issuance of Multiple Prescriptions for Schedule II Controlled Substances," and DEA's "Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies," as agency guidance establishing a pharmacy's corresponding responsibility. 77 Fed. Reg. at 62341. "Settled Agency precedent has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist

[4] *See also Holiday CVS*, 77 Fed. Reg. at 62323 (CVS Vice President of Pharmacy Operations testified that "[w]e understand that it's our responsibility to provide our stores the tools and information that they need to do their jobs on a day-to-day basis and in compliance with state, federal and local legislation and requirements.").

or pharmacy knows or has reason to know that the prescription is invalid." *Id.* (internal quotation marks and citation omitted).

b. CVS Is Not Insulated From Its Compliance Personnel's Knowledge.

It is well settled, then, that pharmacies, just like pharmacists, are subject to § 1306.04(a). CVS argues, however, that the scienter requirement set forth in § 1306.04 belongs to the dispensing pharmacist alone. ECF No. 65-1 at 22. And if the dispensing pharmacist does not "know" the prescription is invalid, the pharmacy does not violate the CSA. *Id*. at 22-23. CVS posits that both the "actus reus (the filling of the prescription)" and the required *mens rea* must rest with a single pharmacist. *See id.* at 21.

In CVS's reading of the statute and regulation, the dispensing pharmacist is "*the* pharmacist who must have the scienter." *See id*. at 23 (emphasis added). But this ignores that CSA regulations define "person" to include "any individual, corporation, government or government subdivision or agency, business trust, partnership, association, or other legal entity." *See* 21 C.F.R. §§ 1300.01, 1306.02 (incorporating the definition of "person" in § 1300.01). The term "person" includes corporations like CVS. Interpreting "person" to exclude corporate pharmacies would be contrary to the plain language of the regulations. *Accord United States v. Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1190 (E.D. Ky. 2017) ("[B]ecause Congress used the terms 'practitioner' and 'pharmacist' elsewhere in § 1306.04(a), it certainly could have used those words in lieu of the term 'person' if it had truly intended to limit liability under these provisions to practitioners and pharmacists.").

CVS admits that courts have rejected the scienter theory it posits here. ECF No. 65-1 at 23 n.13 (citing *United States v. Walmart Inc.*, No. 20-cv-01744-CFC, 2024 WL 1051017, at *5-9 (D. Del. Mar. 11, 2024) and *Appalachian Reg'l Healthcare*, *Inc*., 246 F. Supp. 3d at 1188-90). In *Walmart*, the court held that a "compliance team member's knowledge of the ineffectiveness of a

prescription," such as a prescription written by a prescriber who that employee knew to be writing prescriptions outside the course of ordinary medical practice, is "chargeable to the corporation itself," and the company may be held liable even if an "unknowing pharmacist" filled the prescription. 2024 WL 1051017 at *8-9; *see also Ridley's Family Mkts., Inc.*, 2021 WL 2322478, at *3 (complaint need not connect specific pharmacists with specific prescriptions). CVS has not cited a single case, nor has the Government located one, holding that a pharmacy entity does not have liability under the CSA for filling prescriptions the pharmacy knew were invalid.

CVS nonetheless attempts to distinguish *Walmart* by arguing that the court did not address the text of § 1306.04 and that *Walmart* is limited to "common-law challenge[s]" to corporate scienter. ECF No. 65-1 at 23 n.13. Contrary to CVS's claim, the *Walmart* court addressed the CSA language and reasoned that it does not dictate a specific outcome, 2024 WL 1051017 at *6, and that because the *mens rea* under § 1306.04 is "knowingly . . . not recklessly, willfully, intentionally, or purposely[,] . . . a Walmart compliance team member's knowledge of the ineffectiveness of a prescription is chargeable to the corporation itself and the filling of that prescription by Walmart with the knowledge of the ineffective prescription imputed to it, constitutes a violation of § 1306.04(a)." *Id.* at *8 (internal quotations omitted). The court interpreted the text of the statute and implementing regulation to hold that the pharmacy, through its corporate compliance personnel, had the requisite knowledge. *Id.*; *see also Ridley's Family Mkts., Inc.*, 2021 WL 2322478, at *3 ("Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.") (citations omitted).

As in *Walmart*, CVS's corporate-level employees received information about the validity of prescriptions. *See, e.g.*, Compl. ¶¶ 188-89, 200-210. The Complaint is replete with detailed

allegations that CVS's corporate-level employees knew about pill mill prescribers and did not share that information with pharmacists and, in some particularly egregious cases, even instructed pharmacists to continue filling the invalid, pill mill prescriptions. *See, e.g.*, *id.* ¶¶ 217-218. The knowledgeable corporate personnel included CVS executives, as well as its corporate compliance team specifically responsible for CSA compliance, including responsibility for reviewing prescribers for potential improper conduct, among other duties. *Id.* at ¶¶ 18, 128, 181-83, 192-205. CVS's corporate-level employees' conduct predictably led to CVS pharmacists filling pill mill prescriptions long after CVS knew the prescriptions were invalid.[5]

Adopting CVS's reading of § 1306.04 would allow CVS to immunize itself from CSA liability. Under this reading, no matter what CVS knew about a prescriber or even a specific prescription, CVS would not violate its CSA obligations so long as that information was not conveyed to the particular pharmacist on duty. Even if another pharmacist in the store was aware that the prescription was invalid, CVS could evade liability so long as no one told the dispensing pharmacist. Under such a reading, corporations could easily avoid CSA requirements by siloing information. Holding pharmacies like CVS accountable demands a reading of § 1306.04 that gives

[5] CVS's notice of supplemental authority, ECF No. 68, mischaracterizes the government's theory and provides authority that is inapposite. The Government does not allege violations of the CSA or FCA simply because CVS failed to implement a corporate block on certain pill mill prescribers. Rather, the Government alleges that CVS filled prescriptions written by pill mill prescribers that "were not valid." Compl. ¶ 217. Contrary to CVS's claims, the Complaint does not allege that CVS had to implement any particular compliance program or method to comply with the law. Rather, the Complaint alleges that the law requires that CVS comply with its obligations under the CSA and FCA, whether by corporate compliance programs or by giving its pharmacists the tools and time to comply with the law, and that CVS failed to do so. There is nothing inconsistent with this position in the decision issued by the California State Board of Pharmacy. In fact, the decision explicitly endorses CVS providing notifications to pharmacists that doctors have been "identified" as "potentially issuing prescriptions that are not valid." ECF No. 68-1 at 40. This is the kind of information that the Complaint specifically alleged CVS did not provide to its pharmacists. *See* Compl. ¶ 189 (alleging that CVS had no system to warn its pharmacists that a specific prescriber had engaged in a "pattern of invalid prescriptions").

meaning to pharmacies' obligations at the entity level. *See In re Nat'l Prescription Opiate Litig*. ("*Opiate II*"), No. 17-md-2804, 2020 WL 5642173, at *2 (N.D. Ohio Sept. 22, 2020) (pharmacies "cannot collect data as required . . . but then *do nothing* with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled.") (emphasis in original); *City & Cty. of San Francisco v. Purdue Pharma L.P.*, 620 F. Supp. 3d 936, 996 (N.D. Cal. 2022) ("To prevent the harms that result from illegitimate prescribing, pharmacies and pharmacists have a 'corresponding responsibility' to develop and maintain effective systems to identify and prevent dispensation of illegitimate prescriptions.") (citing § 1306.04(a)).[6]

The Complaint sufficiently alleges facts to "raise a reasonable expectation" that "discovery will reveal evidence" that CVS knew about pill mill prescribers—those identified in the Complaint and others—and nonetheless allowed its pharmacists to continue filling those prescribers' invalid prescriptions. *See Sepulveda-Villarini*, 628 F.3d at 30 (quoting *Twombly*). Nothing more is needed at this stage.

3. The Government Adequately Alleges CVS Knowingly Filled Invalid Refills.

CVS asserts that the Complaint fails to state a claim for improper refills for Schedule III and Schedule IV prescriptions, arguing that the Government has alleged "no facts to support this claim." ECF No. 65-1 at 24. CVS improperly narrows its analysis to two sentences in the Complaint at paragraphs 115 and 372. *See id*.

However, courts evaluating the plausibility of a claim consider the claim in the context of all the facts alleged and may further draw on experience and common sense. *Ocasio-Hernandez*

[6] Established agency principles also provide that a corporation is liable for failing to share information with agents if the failure violates a regulatory duty. *See* Restatement (Third) of Agency § 5.03 cmt. d(7)(g) (courts have imputed knowledge where a principal has a "duty to transmit all material facts to the agent" and "regulatory objectives would be undermined were principals to limit disclosure of material facts to their agents"). A principal cannot evade liability when its agents engage in conduct they expect will cause others to engage in wrongful acts.

v. Fortuno-Burset, 640 F.3d 1, 14-16 (1st Cir. 2011); *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009) (explaining that "the complaint should be read as a whole, not parsed piece by piece"). To survive a motion to dismiss, a pleading is only required to allege plausible entitlement to relief that gives the opposing party fair notice of the claim and the grounds on which it rests. *Iqbal*, 556 U.S. at 678; *Ocasio-Hernandez,* 640 F.3d at 8.

The Complaint accomplishes this task by alleging, among other facts, that on at least hundreds of occasions from January 7, 2015, to the present, CVS pharmacists dispensed Schedule III and IV drugs in violation of the CSA's restrictions on refills. *See* Compl. ¶¶ 115, 372. The Complaint cites the CSA restrictions in 21 U.S.C. § 829(b) and 21 C.F.R. § 1306.22 and explains that they prohibit refilling Schedule III or IV prescriptions more than five times or more than six months after the prescription was written. *Id.* ¶ 53. As noted above, the Complaint also describes the polices, practices, and conditions under which CVS pharmacists filled these refills. *See id.* ¶¶ 105-210. The Complaint, therefore, puts CVS on notice of the allegation that CVS pharmacists refilled prescriptions for Schedule III and IV drugs more than five times, or more than six months after those prescriptions were written, on hundreds of occasions beginning in January of 2015. As discussed above, the Government is not required to provide detailed factual allegations or identify each invalid refill at this stage. *See*, *e.g.*, *Opiate I*, 477 F. Supp. 3d at 629 n.25.

C. <u>The Complaint Plausibly Alleges That CVS Violated the FCA.</u>

In addition to allegations that CVS violated the CSA, the Complaint adequately alleges that CVS violated the FCA when it knowingly submitted claims to Federal Healthcare Programs for controlled substance prescriptions bearing one or more unresolved red flags indicating the prescriptions were not valid, not for medically accepted indications, and/or were not medically necessary. Compl. ¶¶ 211, 213-216. In support, the Government has pled example false claims

for specific Patients #7 through #10 and in Attachment 2, satisfying the heightened pleading standard of Rule 9(b) for the reasons set forth below. *Id.* ¶¶ 355-369, Attachment 2.

Significantly, CVS does not move to dismiss the Government's FCA claims based on Attachment 1, which identifies example prescriptions filled by CVS and written by prescribers CVS knew to be pill mills. CVS also does not move to dismiss allegations as to Patients #1 through #6, whom the Government alleges received invalid prescriptions from CVS and subsequently died by overdose, with the very drugs dispensed by CVS still in their systems. Instead, CVS only argues that the Government has not satisfied its pleading burden under the FCA as to its claims contained in Attachment 2 to its Complaint, which are examples of prescriptions bearing one or more unresolved egregious red flags filled by CVS and billed to Federal Healthcare Programs. Specifically, CVS contends that the Government has not adequately pled falsity, materiality, or knowledge as to the claims contained in Attachment 2. As set forth below, CVS's arguments are without merit, and the entirety of the Government's FCA claims should proceed to discovery.

1. The Government Has Adequately Alleged Falsity.

Federal Healthcare Programs do not pay for prescription drugs that are not medically necessary, but instead are for recreational use, abuse, or addiction. For instance, Medicare covers only drugs that are used for a "medically accepted indication" and that are dispensed upon a valid prescription under state law. Compl. ¶¶ 80-82; 42 U.S.C. §§ 1395w-102(e)(1), (4); 42 C.F.R. §§ 423.100, 423.104(h). Similarly, Medicaid coverage extends only to "prescribed drugs," and does not include drugs dispensed pursuant to invalid prescriptions. Compl. ¶ 86; 42 U.S.C. § 1396d(a)(12). TRICARE will pay only "for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care. However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and

whether or not obtained by legal means." Compl. ¶ 92; 32 C.F.R. § 199.4(e)(11). Claims for controlled substance prescriptions are false under the FCA where, as here, they do not meet the Government's requirements for reimbursement. 31 U.S.C. § 3729(a)(1); *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 117 (D. Mass. 2021) ("Courts have interpreted falsity to encompass a theory of liability based on non-compliance with regulatory instructions.") (internal quotations omitted); *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 84 (2d Cir. 2017) (allegations "detail[ed] specific and plausible facts" from which the court could "easily infer . . . that [defendant] systematically falsified its records to support false claims that [medical services] were medically necessary and thus reimbursable").

Courts have imposed liability under the FCA based on at least two types of false claims: claims that are "factually false" and claims that are "legally false." *See Journey to Hope*, 728 F. Supp. 3d at 258. A claim is factually false when it is "untrue on its face," *id.*, whereas a claim is legally false when it includes a certification misrepresenting compliance with statutory, regulatory, or contractual requirements. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 180, 190-91 (2016). The First Circuit has taken "'a broad view' of what may constitute a false claim or statement to avoid improperly foreclosing FCA liability and has rejected frameworks that turn on legal versus factual falsity." *Journey to Hope*, 728 F. Supp. 3d at 257 (citing *United States ex rel. Brigham & Women's Hosp.*, 678 F.3d 72, 85 (1st Cir. 2012)). Rather than employ a "sharp definition of falsity," this Circuit has stated that "liability is constrained by strict enforcement of the Act's materiality and scienter requirements." *Id.* at 258 (internal citation

omitted).[7] Here, the Complaint more than adequately alleges falsity under this framework.

a. CVS's Claims Were Factually False.

The Government has adequately alleged that CVS's claims to Medicare were factually false because the PDEs contained false, inaccurate, and incomplete information. Compl. ¶ 84. The Complaint alleges that CVS filled hundreds of thousands of prescriptions that had no medically accepted indication, were not valid, and/or were not medically necessary. *Id.* ¶¶ 213, 357-369, Attachment 2. These included prescriptions for the trinity, early fills of controlled substance prescriptions, and prescriptions for extremely high doses and excessive quantities of opioids. *Id.* CVS caused Plan Sponsors to submit false, inaccurate, and incomplete PDE data to Medicare for these prescriptions and to inaccurately designate these drugs as covered Part D drugs. *Id.* ¶¶ 63-84; 213-16; 380-83. The Complaint also alleges that CVS submitted, or caused to be submitted, data to TRICARE and state Medicaid programs that were false, inaccurate, and incomplete, and CVS caused those programs to make payments for prescription drugs that were medically unnecessary and/or based on invalid prescriptions. *Id.* ¶¶ 88-90; 94-96; 213-16; 380-83.

CVS incorrectly asserts that "the government's theory of [falsity] is identical to, and derivative of, its theory under the CSA." ECF No. 65-1 at 25. Based on this mischaracterization, CVS argues that to plead falsity, the Government was required, and failed, to allege that "doctors wrote [the prescriptions at issue] unlawfully, outside the usual course of professional treatment." *Id.* Without those allegations, CVS asserts that the presence of alleged red flags alone does not establish invalidity, and the Government has not adequately pled falsity as to the claims in

[7] CVS's Motion argues only that the Government has not adequately alleged factual falsity; it does not address the Government's allegations that CVS also submitted claims including express and implied false certifications to Federal Healthcare Programs. The Government addresses both theories for completeness.

Attachment 2. *Id.* As set forth in Section V.B., however, the Government's CSA claim is separate from its FCA claim. While certain elements of both claims may rely on similar factual proof at trial, the Government's FCA claim is neither derivative of, nor need be predicated upon, a finding that CVS violated the CSA.

i. Prescriber Information is Not Required to Plead an FCA Claim.

CVS's argument also fails because the Government need not assert allegations related to the identity of the prescriber, including whether the prescriber wrote the prescriptions at issue unlawfully, to plausibly plead that *CVS* submitted false claims. *See* 31 U.S.C. § 3729(a) (imposing liability on any "*person*" who knowingly submits or *causes to be submitted* false claims on the Government). Under the FCA, a "person" includes not just individuals, but also private corporations. *See Cook Cty.*, 538 U.S. at 125 ("While § 3729 does not define the term 'person,' we have held that its meaning has remained unchanged since the original FCA was passed in 1863. There is no doubt that the term extended to corporations[.]") (internal citing references omitted); *see also United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 506 (6th Cir. 2007) (explaining that when "the corporation has committed the fraudulent acts, it is the identity of the corporation, not the identity of the natural person, that [the Government] must necessarily plead with particularity"). In any event, the Complaint identifies the CVS store number and prescription number for each sample claim, which allows CVS to identify which of its pharmacists filled the prescription and the prescriber who wrote the prescription. *See* Attachment 2. Because the Government's FCA claims are not predicated upon the specific prescriber's conduct, and are instead based on *CVS's own conduct*, CVS's citations to cases regarding medical judgments of prescribers are inapposite. *See* ECF No. 65-1 at 26.

Moreover, some of the prescriptions listed in Attachment 2 are false, *i.e.* non-reimbursable, due to their combination with other drugs. When certain combinations were prescribed by multiple

prescribers, the physicians writing the individual prescriptions might have acted reasonably, but the combination filled at CVS could still be invalid. Consequently, focusing on the medical judgment of any particular prescriber is not dispositive as to whether a claim was false.

ii. Courts Have Held Allegations of Unresolved Red Flags Are Highly Indicative of Invalid Prescribing.

The Government has alleged that claims for controlled substance prescriptions are false under the FCA where they do not meet the Government's statutory and regulatory requirements for reimbursement. *See* 31 U.S.C. § 3729(a)(1); Compl. ¶¶ 80-83 (alleging that Medicare will not cover prescriptions for controlled substances issued for an illegitimate medical purpose, are not used for a medically accepted indication, and are not dispensed upon a valid prescription that complies with all applicable state laws); ¶ 86 (alleging that Medicaid coverage does not extend to drugs dispensed pursuant to invalid prescriptions); ¶ 92 (alleging that TRICARE coverage only extends to "medically necessary prescription drugs" and "cannot be authorized to support or maintain an existing or potential drug abuse situation" (quoting 32 C.F.R. § 199.4(e)(11)). As stated above in Section V.B.1(c), because courts have recognized numerous red flags, including the same red flags identified in the Complaint, to be highly indicative of prescriptions that lack a valid medical use, the Government has plausibly alleged that the unresolved red flags present here resulted in the submission of false claims to Federal Healthcare Programs.

iii. Wal-Mart Stores East, LP is Distinguishable.

CVS relies heavily on *United States ex rel. Sheoran v. Wal-Mart Stores East, LP*, 858 F. App'x 876 (6th Cir. 2021) in support of its argument that the Government has not adequately pled a false claim here. ECF No. 65-1 at 25-26. In *Wal-Mart Stores East, LP*, a *qui tam* in which the Government declined intervention, the relator alleged that Wal-Mart filled improper prescriptions for high dosages of opioids, relying on a "Medical Expenses Summary" that listed *one* patient's

prescriptions and their costs. 858 F. App'x at 877-78. Based on the low cost of one to two dollars charged to the patient per prescription, the relator speculated that the patient "must have received government reimbursement through Medicare or Medicaid" but provided no evidence that any claim was actually submitted to a Federal Healthcare Program. *Id*. As a result, the Sixth Circuit held that the relator failed to allege that any particularized claims were presented to the United States, thus failing to meet the Rule 9(b) standard. *Id.* at 878-89. The Sixth Circuit affirmed the trial court's decision to dismiss the relator's conclusory allegation that prescriptions for "high doses" of "450-1200 mg" of "methadone, morphine sulfate, and/or oxycodone" were filled and were false because that allegation was "directly contradict[ed]" by the examples relator offered in support, which showed that not one prescription for those opiates exceeded 30 mg over a five-year period. *Id.* at 881; *United States ex rel. Sheoran v. Wal-Mart Stores East, LP*, No. 13-cv-10568, 2019 WL 3936393, at *3 (E.D. Mich. Aug. 20, 2019), *aff'd*, 858 F. App'x 876 (6th Cir. 2021) . In concluding that the relator failed to establish falsity, the Sixth Circuit also pointed to the lack of "medical information" in the complaint, which in its view, made it "impossible to evaluate whether the doses were too high." *Wal-Mart Stores East, LP*, 858 F. App'x at 879. CVS relies on this statement to argue that, first, the United States is required to plead specific facts about the medical judgment of each doctor writing each prescription, and second, that judgments are subjective and thus cannot be false anyway. ECF No. 65-1 at 24-27.

Wal-Mart Stores East, LP is readily distinguishable from the Complaint for at least two reasons. First, as discussed previously, courts have recognized that the red flags such as those cited in the Complaint indicate that prescriptions are not for valid medical uses. *See* Section V.B.1(c). CVS itself identified these red flags internally, warned its pharmacists to check for prescriptions with such red flags and resolve them prior to dispensing, and even set up—but then

removed—a system that could have attempted to prevent its pharmacists from filling red flagged prescriptions. *See* Compl. ¶¶ 107-13, 194-98. Unlike the relator's allegations in *Wal-Mart Stores East, LP*, the Complaint here alleges that CVS's internal policies identified a controlled substance prescription presenting with more than 50 MME as having a red flag that required resolution. *Id*. ¶ 112. All high daily dose examples included in the Complaint are controlled substance prescriptions presenting with at least 300 MME—***six times*** the amount set forth as a red flag in CVS's own documents. *See* Attachment 2. CVS now asks this Court to conclude that its own designation of a list of red flags and its internal processes to ostensibly prevent pharmacists from filling prescriptions with those characteristics were meaningless, *see* ECF 65-1 at 5 n.2, which is not credible and, in any event, is inappropriate at the pleading stage.

Second, *Wal-Mart Stores East, LP* is narrower than CVS claims. There, the court held that relator's FCA complaint did not meet Rule 9(b)'s particularity requirements where it was based on unsupported claims and "bare-bones assertion[s]." 858 F. App'x at 879. Here, however, the Complaint alleges in detail more than 9,500 examples of prescriptions that have met the "who," "what," "when," "where," and "how much" required under Rule 9(b). For example, the Complaint alleges the following information for Patient #8 (also listed in Attachment 2):

- **Who**: CVS Pharmacy with NPI 1730283656
- **What**: Submitted three prescription claims to Medicare for (1) 120 tablets of oxycodone/apap 10/325 mg (payment $72.62); (2) 120 tablets of carisoprodol 350 mg (payment $6.49); and (3) 120 tablets of diazepam 10 mg (payment $15.70), which combined constituted the trinity cocktail, a known red flag.
- **When**: September 13, 2017
- **Where**: CVS Pharmacy with NPI 1730283656
- **How**: The Complaint alleges in detail that CVS submitted, or caused to be submitted, claims like these for the trinity cocktail and submitted PDE claims to Medicare for each prescription. The reimbursements for these prescriptions were sent into an account in

> CVS's control. CVS also certified compliance with government statutory and regulatory requirements when submitting these claims.

Compl. ¶¶ 360-62. The Complaint further alleges additional dates on which the same CVS Pharmacy filled the trinity cocktail for Patient #8, along with numerous other examples of prescription claims for the trinity cocktail, controlled substances with a daily MME of more than 300, and early prescription refills.[8] *See id.* ¶ 361, Attachment 2. These sample claims are representative of the broader class of claims—in terms of their general time frame, substantive content, and relation to the allegedly fraudulent scheme. No more is required at this stage.

b. The Government Alleged CVS's Claims to Medicare and Medicaid were Legally False Based on Express Certification Theory.

The Government has also adequately alleged that CVS's claims to Medicare and Medicaid were legally false because the claims included express false certifications of compliance with federal law. Medicare requires Plan Sponsors to certify that the PDE data were accurate, complete, and truthful and that they have complied with laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. §§ 423.505(k)(1)-(3); Compl. ¶¶ 73-79. Regulations further require that contracts between Part D Plan Sponsors and downstream entities contain language that requires the pharmacy to comply with applicable federal laws and certify to the accuracy, completeness, and truthfulness of the data. 42 C.F.R. § 423.505(i)(4)(iv); Compl. ¶¶ 75, 78. By submitting requests for reimbursement to Plan Sponsors for such invalid prescriptions, CVS

[8] In another declined *qui tam*, a district court recently cited *Wal-Mart Stores East, LP* with approval in concluding that the relator had failed to sufficiently allege falsity. *United States ex rel. Publix Litig. P'ship, LLP v. Publix Super Mkts., Inc.*, No. 22-cv-02361-TPB-AAS, 2025 WL 1381993, at *8-9, n.10 (M.D. Fla. May 13, 2025). In *Publix*, however, the court noted that "Relator does not show one exemplar prescription that was submitted to the government" and found that the examples "mostly consist of a list of patients that received prescriptions for opiates at Publix pharmacies" without alleging that any of those prescriptions were "actually invalid." *Id.* at *8. The *Publix* decision, like the *Wal-Mart Stores East, LP* decision, is therefore easily distinguishable. Unlike the detailed Complaint here, those cases did not provide any examples of specific false claims for alleged invalid prescriptions submitted to Federal Healthcare Programs.

caused Plan Sponsors to certify that PDEs for those prescriptions were accurate, complete, and truthful when, in fact, they were not. Compl. ¶ 214; *see also United States ex rel. Bassan v. Omnicare, Inc.*, No. 15-cv-4179, 2021 WL 1063784, at *8-10 (S.D.N.Y. Mar. 19, 2021) (government adequately alleged that defendant pharmacy submitted express false certifications to Medicare when it sought reimbursement for prescriptions that did not comply with federal law). Medicaid requires similar attestations from participating providers. Compl. ¶¶ 89-90. These false express certifications of compliance to Medicare and Medicaid rendered CVS's claims false.

Furthermore, the Government has adequately alleged that CVS's claims to Federal Healthcare Programs were false because the claims impliedly certified compliance with the legal requirements for reimbursement set forth above when, in fact, CVS had not complied. The Supreme Court has made clear that a defendant's claim for payment is impliedly false when the defendant makes "specific representations about the goods or services provided" but does not disclose "noncompliance with material statutory, regulatory, or contractual requirements." *Escobar*, 579 U.S. at 188-90. Here, CVS submitted, or caused to be submitted, claims to Federal Healthcare Programs for controlled substance prescriptions with specific representations about the prescriptions, while simultaneously failing to disclose that the prescriptions were not for medically accepted indications, were invalid, and/or were not medically necessary. 42 C.F.R. §§ 423.505(h)(1), (i)(4)(iv); 32 C.F.R. § 199.4(e)(11); Compl. ¶ 90 (describing Rhode Island Medicaid Provider Agreement, which requires providers to certify "that the goods or services listed were medically necessary, authorized (if the goods or services claimed required preauthorization under existing statutes or regulations), and actually rendered to the RI Medicaid beneficiary"); *see also* Compl. ¶¶ 74-75, 92, 96, 380-83. Similarly, by submitting, or causing to be submitted, claims for prescriptions it filled to Medicaid and TRICARE, CVS impliedly certified that the prescriptions

were medically necessary when they were not. *Id.* ¶¶ 89-90, 92, 96, 380-83. These implied false certifications of compliance to Federal Healthcare Programs rendered CVS's claims false.

2. The Government Has Adequately Alleged Materiality.

The FCA defines "material" to mean that it has a "natural tendency to influence," or is "capable of influencing," the Government's payment decision. *See* 31 U.S.C. § 3729(b)(4). The Supreme Court in *Escobar* identified the factors relevant to evaluating materiality under the FCA as including: (1) how the Government characterizes the violation; (2) whether the Government refuses to pay claims when it has actual knowledge of fraud; and (3) whether noncompliance is "minor or insubstantial" or instead goes "to the very essence of the bargain." 579 U.S. at 193-95, n.5. No one factor is dispositive. *Id*. at 194-95. The First Circuit, on remand in *Escobar*, denied the defendant's motion to dismiss and stated that evaluating the sufficiency of an FCA claimant's allegations as to materiality demands a "holistic" analysis. 842 F.3d at 109. In applying this "holistic" analysis, the First Circuit found that the relators had sufficiently alleged that the defendant's misrepresentations were material for three reasons. *Id.* at 110. First, relators alleged in their complaint that compliance with licensing and supervision Medicaid regulations, which relators had alleged defendants violated, was a condition of payment. *Id.* Second, because Medicaid had made it clear that it expected providers to have certain credentials, the related regulations went to the "very essence of the bargain," and failing to comply with those regulations was "strong evidence" of materiality. *Id*. Last, even though the defendants claimed that the Government continued to pay claims with knowledge of the violations, the court found that "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance," and relators had sufficiently stated a claim under the FCA to survive the motion to dismiss. *Id.* at 111-12.

CVS argues that the Government has not pled materiality because the Government was aware of all information available in Attachment 2, asserting that even if filling the prescriptions was unlawful, the unlawfulness was not material. ECF No. No. 65-1 at 27. CVS's argument fails because (i) the Government has plausibly alleged that compliance with federal and state laws was material to the United States's decision to reimburse; and (ii) the Government did not have actual knowledge that CVS was not complying with federal and state laws.

a. The Government Plausibly Alleges that Compliance with Federal and State Law was Material to the Decision to Reimburse.

The Government plausibly alleges that CVS's compliance with federal and state requirements was material to the United States's decision to reimburse claims for controlled substances. First, the Secretary of HHS declared the opioid epidemic a national public health emergency under federal law, Compl. ¶ 102, and Federal Healthcare Programs have repeatedly set forth the importance of compliance with federal and state requirements as it relates to the prescribing of and payment for controlled substances, *id.*, ¶¶ 97-104. Second, Medicare Part D expressly conditions payment on the submission of accurate, truthful, and complete claims data. *Id.* ¶ 76 (citing 42 C.F.R. §§ 423.505(k)(1), (k)(3)). Medicaid typically conditions payment on compliance with federal and state laws and regulations, *id.* ¶¶ 89-90 (providing example agreement certifying medical necessity), and TRICARE requires pharmacies to comply with program requirements, including anti-abuse provisions, *id.* ¶ 96 (citing 32 C.F.R. §§ 199.9(a)(4), (b), (c)(2)). The law also vests pharmacies and pharmacists with obligations to ensure they fill only legitimate (i.e., not false) prescriptions for controlled substances. *Id.* ¶ 41 (citing 21 C.F.R. § 1306.04(a)). CVS's noncompliance with these material requirements for reimbursement was neither minor nor insubstantial, but repeated and pervasive, filling and billing Federal Healthcare

Programs for hundreds of thousands of prescriptions that were not for medically accepted indications, were invalid, and/or were not medically necessary.

b. The Government Did Not Have Actual Knowledge of CVS's Noncompliance with Federal and State Law.

Despite CVS's assertions to the contrary, the Government did not have actual knowledge of CVS's noncompliance. Due to the enormous volume of claims received and the importance of timely payment to providers, the "Medicare program has historically paid claims quickly without verifying the accuracy of the claims before payment." *See United States ex rel. Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1206 (9th Cir. 2019); *United States v. Louthian*, 756 F.3d 295, 297-98 (4th Cir. 2014). Instead, the Government relies on *providers* to submit "accurate, complete, and truthful" claims data, 42 C.F.R §§ 423.505(k)(1), (k)(3), and will seek "reimbursement or recoupment if it later determines that the claim should not have been paid." *Godecke*, 937 F.3d at 1206. The same is true for Medicaid and TRICARE. *Omnicare, Inc.*, 2021 WL 1063784, at *8 ("Obviously, the Government would not have reimbursed for these claims [submitted to Medicare, Medicaid, and TRICARE] had it known that they were dispensed without valid prescriptions."). Indeed, the Complaint alleges that Federal Healthcare Programs have previously denied payment or sought recoupment for payment already made when controlled substance prescriptions were not valid. Compl. ¶ 103. In addition, the United States has litigated and settled cases against pharmacies for submitting or causing the submission of false claims for controlled substance prescriptions to Federal Healthcare Programs that lacked valid prescriptions, were not for a medically accepted indication, and/or were not medically necessary. *Id.* ¶ 104.

Moreover, identifying unlawful prescriptions from the PDE data alone for prescription claims submitted to Medicare Part D, as CVS argues, would require the Government to perform complex, real-time analysis spanning multiple claims submitted at different times and, potentially,

from different pharmacies, with serious implications for timely claim payment. This analysis would occur after the prescription was filled and without the benefit of information concerning the legitimacy of the prescription available to the CVS pharmacist who filled it, such as (1) the full dispensing history for the patient; (2) the patient's diagnosis; (3) any drug utilization review ("DUR") reports; (4) information learned from contacting the prescriber; and (5) information contained in the state-run Prescription Drug Monitoring Program. *See id*. ¶ 110.

In fact, the Complaint alleges numerous instances where CVS had information the Government did not. For example, CVS pharmacists filled unlawful prescriptions from prescribers known to CVS to be pill mill prescribers based upon reports from its own pharmacists—information not known to the Federal Healthcare Programs at the time they reimbursed the claims. *See, e.g.*, *id.* ¶¶ 218-35, 247-317, 319-32 & Attachment 1. Likewise, Federal Healthcare Programs would have been unaware that CVS pharmacists created a fake home delivery account and allowed a doctor to pick up prescriptions he ostensibly wrote for 66 different patients. *See, e.g.*, *id.* ¶¶ 291-304, & Attachment 1, Patient #134.

Moreover, CVS—not the Government—was obligated to ensure that its stores did not fill unlawful prescriptions for controlled substances and, unlike the Government, had the knowledge and means to do so. *See Rock Island, A. & L. R. Co. v. United States*, 254 U.S. 141, 143 (1920) ("Men must turn square corners when they deal with the Government."). The Federal Healthcare Programs were entitled to rely upon CVS to perform those obligations properly and process claims on the understanding that the claims were for valid, reimbursable prescriptions.

Finally, CVS's argument that the Government's continued payment of claims means that "[m]ateriality is not—and cannot—be pled here[,]" *see* ECF No. 65-1 at 31, is also legally incorrect because it would make one factor dispositive to the materiality analysis. The Supreme Court has

stated that the materiality analysis requires weighing multiple factors, and the First Circuit has declared that the materiality analysis is "holistic" and does not rest on one factor. Under that holistic analysis, and on a motion to dismiss, the Government has sufficiently pled materiality.

3. The Government Has Adequately Alleged Knowledge.

In addition to adequately alleging falsity and materiality, the Government has also adequately alleged that CVS acted with the requisite scienter. Although CVS does *not* raise the knowledge element of the Government's FCA claims as a subject of its Motion, it claims in a footnote that the Government has failed to plead knowledge under the FCA as to its Attachment 2 claims. *See* ECF No. 65-1 at 27 n.15. While "arguments raised only in a footnote or in a perfunctory manner are waived," the Government nonetheless responds here to CVS's unpreserved and meritless assertion. *F.T.C. v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 19 n.18 (1st Cir. 2010); *see also Rumford Pharm., Inc. v. City of E. Providence*, 970 F.2d 996, 1000 n.9 (1st Cir. 1992) (for a motion to dismiss, "issues presented in a perfunctory fashion and without developed argumentation are deemed waived" and therefore "merit[] no independent discussion."); *Grella v. Salem Five Cent Sav. Bank*, 42 F.3d 26, 36 (1st Cir. 1994) (arguments in footnotes are "simply insufficient presentation and argumentation of the issue for any meaningful analysis, and we therefore deem it waived.").

CVS's footnote avers that the Complaint failed to sufficiently plead knowledge because (1) "[i]t does not allege any facts about what anyone at CVS actually knew about the Attachment 2 prescriptions or the doctors who wrote them"; (2) it "alleges no facts indicating that anyone at CVS 'disregarded' a red flag by filling any of the Attachment 2 prescriptions without addressing any concerns"; and (3) it "contains no allegations about the persons who filled the Attachment 2 prescriptions or about the circumstances of their doing so." ECF No. 65-1 at 27 n.15. These

arguments are an attempt to impose additional pleading requirements beyond those in the Federal Rules of Civil Procedure.

The Government has plausibly alleged that CVS, as an entity, acted with the requisite scienter when it submitted claims such as those in Attachment 2. As set forth above at Section II.B, "knowingly" under the FCA is defined to include not only actual knowledge, but also "reckless disregard" and "deliberate ignorance." 31 U.S.C. § 3729(b)(1). Knowledge may be "averred generally." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 227-28 (1st Cir. 2004) (quoting Fed. R. Civ. P. 9(b)). Neither a showing of specific intent to defraud, nor actual knowledge, is required. 31 U.S.C. § 3729(b)(1).

The FCA's knowledge requirement does not require the Government to allege the identity of the doctors who wrote the prescriptions. The Government alleged facts describing pharmacists' inability to resolve obvious red flags for the prescriptions they dispensed due to CVS's performance metrics and staffing levels, as well as CVS corporate knowledge of these impediments. Compl. ¶¶ 8-13, 115, 118-191. Specifically, the Government has alleged that CVS knew that it was filling prescriptions bearing egregious red flags of invalidity that were not resolved. *Id*. ¶¶ 13, 151-65, 184-91, 200-11. In addition, the Government alleged that CVS and its pharmacists knew that they were required by law not to fill prescriptions that bore unresolved red flags, including the red flags exemplified by the claims identified in Attachment 2, indicating invalidity, medical inappropriateness, and/or dangerousness. *Id.* ¶¶ 38-52, 72-84, 89-90, 105-117. CVS's corporate department established staffing budget, performance metrics, and incentive-compensation policies that caused pharmacists to dispense these prescriptions too quickly, without carrying out the necessary steps required to resolve them. *Id.* ¶¶ 118-50; 166-75. Indeed, CVS's own policies and pharmacist trainings recognized these red flags as signs of illegitimate use, abuse,

and diversion, and showed CVS's corporate understanding that its pharmacists were required to identify and resolve these red flags prior to dispensing. *Id.* ¶¶ 7, 47, 105-10. The Government, therefore, has plausibly alleged that CVS, at a minimum, acted with reckless disregard of whether the red flag prescriptions they submitted for reimbursement to Federal Healthcare Programs were false, including those identified for Patients #7 through #10 and in Attachment 2.

D. The Government Has Plausibly Alleged Its Common Law Claims.

CVS also argues that the Court should dismiss the Government's properly alleged common law claims of fraud (Count IV), payment by mistake (Count V), and unjust enrichment (Count VI) against CVS because: (1) parties with an adequate remedy at law may not seek equitable relief through unjust enrichment; and (2) the common law claims are subject to dismissal for the same reasons as the Government's FCA claims because they are based on the same factual allegations. ECF No. 65-1 at 31. Courts, however, routinely permit pleading common law claims and violations of the FCA in the alternative. *See, e.g.*, *Journey to Hope*, 728 F. Supp. 3d at 263 (denying motion to dismiss common law claims of unjust enrichment and payment by mistake pled alongside FCA claims); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 130 (D. Mass. 2011) (denying 12(b)(6) motion and rejecting the argument that the Government may not plead alternative theories under the FCA and unjust enrichment); *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 321-24 (D. Mass. 2005) (holding that neither the common law fraud nor the unjust enrichment count should be dismissed, noting that, with respect to the unjust enrichment count, the court would "not force Plaintiff to choose its remedy at this stage of the litigation"). Because "the Government has 'broad power to recover monies wrongly paid from the Treasury'" at common law, *see Journey to Hope*, 728 F. Supp. 3d at 263 (quoting *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 15 (1st Cir. 2005)), and courts permit pleading in the alternative, the Government's common law and equitable claims should not be dismissed.

Moreover, because the Government's common law claims are based on the same factual grounds as its FCA claims, and the Government has met the pleading requirements of Rules 8 and 9(b) for its FCA claims, CVS's Motion to Dismiss the common law claims should be denied.

VI. CONCLUSION

Because the Complaint sufficiently pleads violations of the CSA, FCA, and common law, the United States respectfully requests that the Court deny CVS's Motion to Dismiss.

Respectfully submitted,

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CERTIFICATION OF SERVICE

I hereby certify that on June 4, 2025, I electronically filed the within Opposition with the Clerk of the United States District Court for the District of Rhode Island using the CM/ECF System, thereby serving it on all registered users in accordance with Federal Rule of Civil Procedure 5(b)(2)(E) and Local Rule Gen 305.

Dated: June 4, 2025

/s/ *Rachna Vyas*
RACHNA VYAS
Assistant U.S. Attorney